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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
FAX: 407-475-4769

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-00-22

January 14, 2000

Gaston Lillo, President
Chilean Fish Corporation
8005 N.W. 98th Street
Hialeah Gardens, FL 33016

Dear Mr. Lillo:

On February 17, 1999, the Food and Drug Administration (FDA) conducted an inspection of your fish importing facility, located at 8005 NW 98th Street, Hialeah Gardens, Florida 33016. The Investigator, Carlos W. Hernandez, documented serious deviations from the seafood importing regulations in Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). The violations cause the frozen shrimp being imported and stored by your firm to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) in that they may be injurious to health since the product was processed under conditions not in conformance with the Seafood HACCP Regulations (21 CFR 123). Specifically:

> You must have product specifications that are designed to ensure that the fish and fishery products are not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act, in order to comply with 21 CFR 123.12(a)(2)(i). However, your firm imports raw frozen shrimp from Chile that may be injurious to health if the food safety hazard of sulfiting agents is not controlled.
>
> You must implement an affirmative step that ensures that the imported fish and fishery products are processed in accordance with the requirements of 21 CFR 123.12(a)(2)(ii). However, your firm did not perform an affirmative step that provides documentation that the raw frozen shrimp from Chile was processed in accordance with the requirements of 21 CFR 123.

The above-identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA may detain your imported seafood products without examination until your firm is fully in compliance with the Seafood HACCP regulations.

Please notify this office, in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your written reply should be directed to Paul R. Bagdikian, Compliance Officer, Food and Drug Administration, 6601 Northwest 25th Street (P.O. Box 59-2256), Miami, Florida 33159-2256.

Sincerely,

Edward R. Atkins
Acting District Director
Florida District

cc: Mr. Hugo Herreras, General Manager